

70144-2

(12/12/2013)

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

Megan Pletka
Agent for Micro-Scientific Industries, Inc.
Technology Sciences Group, Inc.
1150 18th ST. N.W., SUITE 1000
Washington, District of Columbia 20036

DEC 12 2013

Subject: Reducing Contact Time and Bridging Microorganisms to in Opti-cide-3 Wipes
EPA Reg. No. 70144-2
Amendment Letter dated June 11, 2013

The labeling referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), is acceptable.

Submit and/or cite all data required for registration/reregistration of your product under FIFRA section 3(c)(5) and section 4(a) when the Agency requires all registrants of similar products to submit such data.

If the above conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA section 6(e). Your release for shipment of the product bearing the amended labeling constitutes acceptance of these conditions.

A stamped copy of your labeling is enclosed for your records. This labeling supersedes all previously accepted labeling. The next label printing of this product must use this labeling unless subsequent changes have been approved. You must submit one (1) copy of the final printed labeling before you release the product for shipment with the new labeling. In accordance with 40 CFR 152.130(c), you may distribute or sell this product under the previously approved labeling for 18 months from the date of this letter. After 18 months, you may only distribute or sell this product if it bears this new revised labeling or subsequently approved labeling. "To distribute or sell" is defined under FIFRA section 2(gg) and its implementing regulation at 40 CFR 152.3.

If you have any questions concerning this letter, please contact Elizabeth Watkins at (703) 346-0241.

Sincerely,

A handwritten signature in black ink, appearing to read "M. Swindell", is written over the typed name "Marshall Swindell".

Marshall Swindell
Product Manager (33)
Regulatory Management Branch 1
Antimicrobials Division (7510P)

Opti-Cide® 3 Wipes

[ABNs:] {Opti-Cide® 3 Surface Wipes} {Opti-Cide® 3 V Surface Wipes}

[Insert marketing statements, as appropriate, from *Marketing Copy* and/or *Directions for Use*]

Active Ingredients:

n-Alkyl (60% C ₁₄ , 30% C ₁₆ , 5% C ₁₂ , 5% C ₁₈)	
dimethyl benzyl ammonium chloride	0.154%
n-Alkyl (68% C ₁₂ , 32% C ₁₄) dimethyl ethylbenzyl	
ammonium chloride	0.154%
Isopropanol	21.000%
Other Ingredients	78.692%
Total	100.000%

Keep Out of Reach of Children

CAUTION

See back [side] panel for additional Precautionary Statements.

EPA Reg. No. 70144-2 EPA Est. 1130-IL-1

Net Contents: _____ wipes
Net Weight: _____ oz. (_____ g)

Product Order Number: _____



Made in the U.S.A.

[Back/Side Panel(s)]

[Marketing Copy]

[Choose as appropriate]

Antibacterial

Antimicrobial

Bactericidal

Broad Spectrum

Cleaner {Cleans}

Decontaminant

Decontaminates

Disinfectant {Disinfects} {Soft} {Hard} Surfaces in {2} {3} {5} {as appropriate} minutes

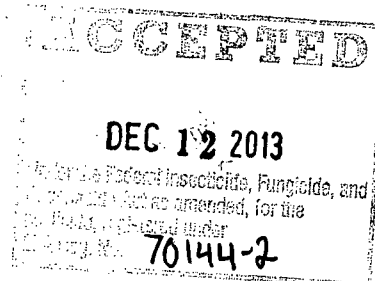
Disinfects

Disinfectant

Cleaner

Deodorizer

Equipment



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{Use on} Pet Care Surfaces

Fragrance free

Fungicidal

Germicidal

General

Sanitizer**

Sanitize{s}**

Hospital

Housekeeping

In-home {Use}

Kills Tuberculosis, BCG {var bovis.}, {TB}, {Gram-positive and Gram-negative} Bacteria, {Enveloped & Non-Enveloped} Viruses*, Fungi in [2] [3] [5] minutes

Kills Bacteria, Viruses*, Fungus on pre-cleaned, hard, non-porous surfaces such as {select from use directions}

Spot Cleans

Kills {names taken from list of approved microorganisms}

Kills {99.9% of bacteria} {or} {germs}

{Pre-cleaning} Instrument {device} Soak

Kills Pandemic 2009 H1N1 Influenza A Virus* {formerly called "swine flu"}

{Medical}/{Surgical}/{Dental} {Veterinary} Equipment Disinfectant Cleaner and Decontaminant

{Surface} Disinfectant/Decontamination Cleaner

{Surface/Facility}{description taken from use directions} Disinfectant Cleaner

{Two minute} {Three minute} Surface Disinfectant

10 Second {Hard} Surface Sanitizer **

Tuberculocidal

Virucidal*

Veterinary/Animal/Pet Care Facility Disinfectant/Cleaner

With {Contains} Fresh {or appropriate descriptive term} Scent

With {Contains} Rust Inhibitor, Biodegradable Detergent

{These Wipes}{These towelettes}-are disposable, single-use towelette wipes pre-saturated with {Opti-Cide® 3}{Opti-Cide® 1}{Opti-Cide® 2}{disinfectant} solution. This product is intended for use on pre-cleaned, hard, non-porous inanimate surfaces in areas where the disinfection of surfaces is required.

[Use Sites]

When used as directed {these towelettes}{these wipes} clean and disinfect surfaces found in animal transport vehicles, animal/pet care facilities, animal/pet housing facilities, animal labs, athletic clubs, automobile interiors, autopsy rooms, barber shops, bathrooms, blood centers, buses, cadaver work [processing] areas, cardiac care labs, cardiac catheterization labs, cardiology units, central sterile supply, central supply areas, child care facilities (day care, infant care, schools), clean rooms, clinical areas, daycare centers, dental facilities, dialysis units, drug preparation facilities, EMS units, endoscopic rooms, equine facilities, esthetician facilities, extended care facilities, field hospitals, food processing facilities (non-food contact surfaces), funeral homes, GI laboratories, gyms, hair salons, health clubs, hospitals, hotels, human transport vehicles, infant care units, institutional facilities, intensive care units, isolation rooms [units], laboratories, large animal care facilities, lasik centers, locker rooms, long-term care facilities, medical facilities (ambulances/EMS/paramedic units, blood banks [centers], clean rooms, dental offices, drug preparation rooms, emergency rooms, infant/child care units, isolation units [rooms] [areas], morgues, neonatal intensive care units, nursing homes, operating rooms, patient care areas, plasma pheresis centers, surgical centers), medical offices, morgues, nail care facilities, nail salons, neonatal units, newborn nurseries, offices, ophthalmic centers, paramedic squads, pathology facilities, pheresis equipment and centers, podiatry offices, police vehicles, prisoner holding areas [lockups], prisons, radiology centers, research laboratories, respiratory care units, salons (beauty, manicure/pedicure, tanning, tattoo), schools, skin care facilities, small animal/pet care facilities, spas, surgical centers and rooms, trailers, train cars, transport equipment, veterinary facilities, veterinary hospitals, workout

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rooms, zoologic centers, zoos and areas/facilities concerned with the hazards of cross-contamination from infectious microorganisms.

{Opti-Cide®3 Wipes}{ Opti-Cide® 3 Surface Wipes}{Opti-Cide® 3 V Surface Wipes}{This product} may be used on ambulance equipment and [patient care] surfaces; anesthesia equipment surfaces, animal cages (aviary, canine, feline, etc.), animal examination tables, animal habitats, athletic/training facility surfaces, baby/infant care surfaces, backboards, bassinets, bathing units, bed rails, beds, blood pressure devices, breathing masks, cabinets, cages, canine care surfaces, changing tables, commodes, computer keyboards [surfaces], counters, CPR training devices, CT equipment/surfaces, curing lights, dental equipment surfaces/devices, dialysis machine surfaces, diving equipment and air packs, doorknobs, EMS equipment/work surfaces, endoscopic devices, equine care surfaces, equipment surfaces, ER surfaces, examination tables, eye glasses, eye protection devices, feline care surfaces, finished surfaces, firefighter turnout gear, foot spa surfaces, funeral home surfaces, goggles, gonial lenses, hard cervical collars/braces, helmets, hospitality and hotel surfaces, incubators, infant care equipment (bassinets, bed railings, cribs, infant incubator-surfaces, tables, warmers (exterior surface), instrument stands, Isolettes®, kennel cages, kennels, keyboards, kidney machines, laboratory equipment/surfaces, laminated surfaces, large animal care surfaces, light lens covers, litter boxes, loupes, mats, manicure/pedicure tables/chairs, mannequins, mayo stands, medical equipment surfaces/devices, medication infusion surfaces microkeratome surfaces, microscopes, monitor knobs, monitors, morgue tables, MRI equipment surfaces, neonatal/nursery surfaces, non-critical devices, nursing station surfaces, OB [obstetrical equipment] surfaces, occupational therapy devices, office fixtures, OR lights, OR surfaces, OR tables, ophthalmic equipment surfaces/devices, optical wear (excluding contact lenses) oxygen hoods, oxygen tents, painted surfaces, patient bed surfaces, patient care devices, patient care equipment surfaces, patient examination tables, patient stretchers, patient transport surfaces, pet care surfaces, pharmacy surfaces, physical therapy equipment (such as bars, chairs, empty whirlpool tanks, etc.), play-care equipment, play mats, pulmonary function equipment, pumps, radiology equipment surfaces, rails, refrigerators (exterior surface), reptile care surfaces, respirators, respiratory care equipment surfaces, respiratory therapy equipment, shampoo bowls, ship [river, ocean, sea vessel] surfaces, showers [floors/walls], sink faucets, skin care equipment/surfaces, sinks, small animal care surfaces, spirometers, stalls, stair chairs, stretchers, surgical equipment surfaces, surgical microscopes, tables, tanks, tanning bed surfaces, tattooing equipment surfaces/devices, telephones, toilets (rims, seats and exterior surfaces), toys, transport van surfaces, transportation equipment surfaces, turn-out gear, ventilators, walls, warmers (exterior surface), wet/dry suits, wheel chairs, whirlpool surfaces, work stations, wrestling mats, X-ray equipment/surfaces and devices/surfaces potentially contaminated with disease-causing microorganisms [and use sites made of glass, metal, Plexiglas®, plastics (i.e., polycarbonate, polypropylene, polyvinylchloride and polystyrene), clear plastic, baked-on painted surfaces, stainless steel, brass, chrome, copper, acrylic, {and non-porous} vinyl}, powder painted coated surfaces, baked painted surfaces, Formica®, glazed tile, leather, laminated surfaces and {other similar surfaces}.

Respiratory illnesses attributable to Pandemic 2009 H1N1 are caused by Influenza A Virus*. This product is a broad-spectrum hard surface disinfectant that has been shown to be effective against Avian Influenza A Virus* ATCC VR-2072 and Influenza Virus* Strain A2/Hong Kong as is expected to inactivate all influenza A viruses* including Pandemic 2009 H1N1 Influenza virus*.

This product has demonstrated effectiveness against Influenza A Virus* and is expected to inactivate all influenza A Viruses* including Pandemic 2009 H1N1 Influenza virus*.

This product has demonstrated effectiveness against Avian Influenza Virus *ATCC VR-2072 and Influenza Virus* Strain A2/Hong Kong and is expected to inactivate all influenza A viruses* including Pandemic 2009 H1N1 {formerly called "swine flu"}.*

[End of Marketing Copy]

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DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

Do not use this product as a baby or skin wipe, or on contact lenses!

This product sanitizes** pre-cleaned non-food contact hard surfaces against the following microorganisms at room temperature with a 10- second contact when used as directed:

- *Staphylococcus aureus* [ATCC 6538]
- *Enterobacter aerogenes* [ATCC 13048]

This product disinfects {effectively kills} the following microorganisms at room temperature) with a 2-minute contact time when used as directed:

- *Acinetobacter baumannii* [ATCC 19606]
- Avian Influenza A (H3N2) Reassortant Virus* [ATCC VR-2072]
- *Escherichia coli*-with extended beta-lactamase resistance {ESBL} {E. coli} [ATCC [BAA-196]
- Hepatitis B Virus* {HBV}
- Hepatitis C Virus* {HCV}
- Herpes Simplex II Virus* {HSV 2} G Strain
- Human Immunodeficiency Virus* {HIV-1} {associated with AIDS}
- Influenza A Virus* {formerly called "swine flu"} H1N1
- Influenza Virus* Strain A2/Hong Kong
- *Klebsiella pneumoniae*- Carbapenem-resistant [ATCC BAA-1705]
- *Listeria monocytogenes* [ATCC 19117]
- *Mycobacterium bovis*, BCG {tuberculosis} {TB}
- *Pseudomonas aeruginosa* [ATCC 15442]
- Rotavirus* Strain WA
- *Salmonella enterica* [ATCC 10708]
- *Serratia marcescens* [ATCC 14756]
- *Staphylococcus aureus* [ATCC 6538]
- Methicillin-Resistant *Staphylococcus aureus* {MRSA} [ATCC 33591]
- *Trichophyton mentagrophytes* {ringworm} [ATCC 9533]
- Vancomycin – Resistant *Enterococcus faecium* {VRE}[ATCC 51299]

For Veterinary / Pet Care Use: In addition to the other microorganisms listed on this label this product kills the following microorganisms at room temperature with a 3-minute contact time or as noted when used as directed:

- *Bordetella bronchiseptica* {kennel cough} [ATCC 10580]
- Bovine Viral Diarrhea Virus* {BVDV – Surrogate Hepatitis C Virus}
- Duck Hepatitis B Virus* {DHBV – Surrogate Hepatitis B Virus}
- Canine Distemper Virus* [ATCC VR-128]
- Canine Para-Influenza Virus* [ATCC VR-666]
- *Chlamydia psittaci* {parrot fever}
- Feline Leukemia Virus*
- Infectious Bovine *Rhinotracheitis* Virus* [ATCC VR-188]
- Murine Norovirus* {Strain MNV-G}
- Poliovirus* I [ATCC VR-58]
- Rhinovirus* [ATCC VR-286]
- *Streptococcus equi* [ATCC 33398]

5 minute contact time:

- Canine Parvovirus*

[For canister dispensing:]

Dispensing Directions:

To start feed, remove cover and discard seal. From the center of the wipe roll, pull-up a wipe corner, twist it into a point and thread it through the hole located on the container cover. Pull through about one inch. Replace cover. Pull out first wipe and tear off at an angle. Remaining wipes feed automatically, ready for the next use. When not in use, keep center cap closed to prevent evaporation.

[For flat pack dispensing:]

Dispensing Directions:

Pull back re-sealable label located on top of pack top about 3/4 of the way. Do not completely remove the label from pack. Remove wipe. Reseal with label to prevent evaporation of solution. To prevent evaporation keep pack sealed when not in use.

[For individual pack dispensing:]

Dispensing Directions:

Open packet, remove and use.

Cleaning and Sanitizing/Disinfection of Surfaces:

Use a fresh {wipe} {towelette} to pre-clean surfaces of all gross filth and heavy soil. Repeat as necessary until surfaces are visibly clean. To effectively sanitize or disinfect the pre-cleaned surfaces, use a fresh {new} {wipe} {towelette} or turn the wipe over to the clean side to thoroughly wet the surfaces and allow surfaces to remain wet for the appropriate time indicated for the purpose intended.

Additional Special Animal /Veterinary/Pet Care Cleaning Sanitizing/Disinfection of Surface Instructions:**

First, remove animal from immediate area; then remove all visible debris, such as animal excrement, and bedding materials, such as blankets, litter, wood chips, hay or straw, and drinking and feeding utensils.

For disinfection of Avian Influenza A, use this product only for surfaces that are not conducive to treatment by immersion or excess liquid (e.g., cages, equipment tables, lab benches, faucet handles, door knobs and similar "high touch" surfaces). Food and drink dispensing and preparation surfaces must be rinsed with potable water prior to use.

HBV, HCV and HIV-1 Precautions: This product effectively inactivates HBV, HCV and HIV-1 on pre-cleaned environmental surfaces/objects previously soiled with blood/body fluids in health care or other settings in which there is an expected likelihood of soiling of inanimate surfaces/objects with blood/body fluids, and in which the surfaces/objects can be associated with the potential for transmission of HBV, HCV and/or the human immunodeficiency virus Type 1 {HIV-1} associated with AIDS. **Special instructions for cleaning and decontamination against HBV, HCV and HIV-1 of surfaces/objects soiled with blood/body fluids:**

Personal Protection: Wear appropriate barrier protection such as gloves, gowns, masks or eye coverings. **Cleaning Procedure:** Blood and other body fluids must be thoroughly cleaned from surfaces/objects before disinfection.

Contact Time: Allow the surface to remain wet for 2 minutes prior to wiping. **Infectious Materials Disposal:** Cleaning materials used that may contain blood/body fluids should be autoclaved and/or disposed of in accordance with local regulations for infectious materials disposal.

This product is not to be used as a terminal sterilant or high-level disinfectant on any surface or instrument that (1) is introduced directly into the human body, either into or in contact with the bloodstream or normally sterile areas of the body, or (2) contacts intact mucous membranes, but which does not ordinarily penetrate the blood barrier or otherwise enter sterile areas of the body. This product may be used to pre-clean or decontaminate critical and semi-critical medical devices prior to sterilization or high-level disinfection.

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Storage and Disposal

Do not contaminate food or feed by storage or disposal.

Storage: Store in a cool, well-ventilated area. **Product and Container Disposal:** Dispose of wipe in trash after use. Do not flush. Tightly close lid between uses to retain moisture. **Non-refillable container.** Do not reuse or refill this empty container. Offer empty container for recycling. If recycling is not available, discard container in trash.

PRECAUTIONARY STATEMENTS

Hazards to Humans and Domestic Animals

CAUTION: Harmful if inhaled or absorbed through skin. Causes moderate eye irritation. Avoid breathing vapors and contact with eyes, skin or clothing. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet. Remove contaminated clothing and wash clothing before reuse.

First Aid

If Inhaled	<ul style="list-style-type: none"> • Move person to fresh air. • If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably by mouth-to-mouth, if possible.
If on Skin or Clothing	<ul style="list-style-type: none"> • Take off contaminated clothing. • Rinse skin immediately with plenty of water for 15-20 minutes.
If in Eyes	<ul style="list-style-type: none"> • Hold eye open and rinse slowly and gently with water for 15-20 minutes. • Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye.
<p>Call a poison control center or doctor for treatment advice. Have the product container or label with you when calling a poison control center or doctor, or going for treatment. You may also contact 1-800-255-3924 for emergency medical treatment information.</p>	

{The First Aid statements' grid format will be used if market label space permits; otherwise a paragraph format will be used.}

Physical or Chemical Hazards

Do not use or store near heat or open flame.

For product or technical information contact {appropriate contact information}.

Manufactured in the U.S.A. for:

{Appropriate company information}

Product Order No: _____

{ } Denotes alternate language

[] Denotes language that does not appear on the market label